AUG 2 3 2004

510 (k) Summary of Safety and Effectiveness for VectorVision® Hip (K040368)

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
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Contact Person: Mr. Rainer Birkenbach

Summary Date: August 13, 2004

Device Name:

Trade name: VectorVision® Hip

Common/Classification Name: VectorVision® Hip, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device
Vector Vision® Hip (K010602)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:
BrainLAB VectorVision is intended to be an intraoperative image guided localization system. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space either on a patients preoperative image data being processed by a Vector vision workstation or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprothesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

Total Joint Replacement (TJR)
Revision surgery of TJR
Tumor resection and bone/joint reconstruction

K040368

Device Description:
BrainLAB VectorV sion® Hip is intended to enable operational planning and navigation in orthopedic surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on an individual 3D-model of the patient's bone, which is either based on a patients preoperative image data or generated through acquiring multiple landmarks on the bone surface. VectorVision® Hip uses the registered landmarks to navigate the needed surgical tools like cup reamer, cup inserter, stem rasp, bone saw and the implant to the planned position. If no implant data is available it is possible to provide information in order to achieve a generally targeted alignment relative to the bone orientation as defined by the operating surgeon.

VectorVision® Hip allows 3-dimensional reconstruction of the relevant mechanical axes and planes of femur and pelvis and alignment of the implants. The VectorVision® Hip software has been designed to read in data of implants and tools if provided by the implant manufacturer and offers to individually choose the prosthesis during each surgery. The VectorVision® Hip software registers the patient data needed for planning and navigating the surgery intra-operatively within the CT free module. The system can be used to generally align too orientations according to the anatomy described and defined by the landmarks acquired by the surgeon. Using the CT based module the patient data can be used additionally for surgery, the patient data is then provided by the CT data stored on a standard data storage media.

Substantial equivalence:
VectorVision® Hip has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of:

- VectorVision® Hip (K 010602)
- Vector Vision® CT-free Knee (K 021306)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstrasse 8
Heimstetten
Germany 85551

Re: K040368
Trade/Device Name: VectorVision® Hip 3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 23, 2004
Received: June 28, 2004

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040368

Device Name: VectorVision® Hip

Indications For Use:

BrainLAB VectorVision is intended to be an intraoperative image guided localization system. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space either on a patient's preoperative image data being processed by a Vector vision workstation or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprothesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

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Revision surgery of TJR
Tumor resection and bone/joint reconstruction

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040368